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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,210	08/07/2003	Dongxiao Zhang	EPIT-001	5792

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,210	ZHANG ET AL	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a method for resurfacing a rabbit antibody, classified in Class 536, subclass 23.5.

II. Claim 14, drawn to a resurfaced rabbit monoclonal antibody, and kit comprising said antibody, classified in Class 530, subclass 388.1.

III. Claims 15-18, drawn to nucleic acid encoding a resurfaced rabbit monoclonal antibody, vector comprising said nucleic acid, and host cell comprising said vector, and method of producing said resurfaced rabbit antibody comprising incubating said host cell, classified in Class 536, subclass 23.5, Class 435, subclasses 320.1, 252.3 and 70.21, respectively.

IV. Claims 19 and 20, drawn to a CRM and kit comprising said CRM, classified in Class 703, subclass 11.

2. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Inventions II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are made of different materials, *i.e.,* the monoclonal antibody protein of Invention II is comprised of amino acid residues whereas the nucleic acid molecule of Invention III is comprised of nucleotides, whereas the CRM of Invention III is a computer readable medium/kit thereof encoding instructions to direct a processor to perform a method. The nucleic acid molecule, vector and host cell thereof are used in the method of that same Invention III to produce the antibody protein of Invention II, and the CRM of Invention IV encodes instructions to direct a processor to perform the method of claim 1.

4. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Invention I produces changes to a rabbit monoclonal antibody to humanize it whereas the method of Invention III produces the actual protein product, the humanized antibody.

5. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)).

In the instant case, the rabbit monoclonal antibody may be humanized by completely substituting human framework regions for rabbit framework regions, rather than substituting selected framework amino acid residues, or by comparing an amino acid sequence of a heavy chain or light chain variable domain of the rabbit antibody to the human heavy chain and light chain variable regions to templates derived from two different human antibodies rather than to the heavy and light chain variable regions of the same human antibody.

Therefore they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art as shown by their different classification (and the searches are not co-extensive) and divergent subject matter, restriction for examination purposes as indicated is proper.

7. **If Applicant elects the method of Invention I**, Applicant is further required to (1) elect a single disclosed species of method steps in the claimed method of producing a resurfaced rabbit monoclonal antibody (***specific steps***, for example, molecular modeling of rabbit antibody to identify surface-exposed amino acid residues as well molecular modeling of non-rabbit human antibody to identify surface-exposed amino acid residues and replacing framework amino acid residues that are not proximal to the CDRs, and/or substituting only amino acid residues that are not in the D-E loop, and wherein the rabbit antibody is homozygous for the VH1-a3 allotype) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

8. **If Applicant elects the method of Invention II**, Applicant is further required to (1) elect a single disclosed species of resurfaced rabbit antibody (***specific antibody***, for example, a rabbit monoclonal antibody homozygous for the VH2-a3 allotype, one in which the framework amino acid residues not proximal to a CDR are substituted from a human antibody and in which the amino acid residues in the D-E loop are not substituted) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. **If Applicant elects the method of Invention III**, Applicant is further required to (1) elect a single disclosed species of nucleic acid molecule encoding a humanized rabbit monoclonal antibody, vector comprising said nucleic acid molecule and host cell comprising said vector and method of incubating host cell to produce said humanized rabbit monoclonal antibody ***(specific antibody***, for example, a rabbit monoclonal antibody homozygous for the VH2-a3 allotype, one in which the framework amino acid residues not proximal to a CDR are substituted from a human antibody and in which the amino acid residues in the D-E loop are not substituted) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

10. **If Applicant elects the method of Invention IV**, Applicant is further required to (1) elect a single disclosed species of CRM encoding specific method steps for directing a processor to perform the humanization of a rabbit monoclonal antibody (***specific steps***, for example, for example, molecular modeling of rabbit antibody to identify surface-exposed amino acid residues as well molecular modeling of non-rabbit human antibody to identify surface-exposed amino acid residues and replacing framework amino acid residues that are not proximal to the CDRs, and/or substituting only amino acid residues that are not in the D-E loop, and wherein the rabbit antibody is homozygous for the

VH1-a3 allotype) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 25, 2006

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